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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,308	03/30/2004	Luca Battistini	2818-200	1799

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,308	BATTISTINI ET AL.	
	Examiner	Art Unit	
	Charlesworth Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 7/17/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Receipt of amendments, filed 7/17/06, regarding to a Brief Description of the Drawings is acknowledged.

Applicant's Claim for Priority

Applicant's argument is not deemed persuasive regarding the claim for priority from the parent application 10/137,699, filed May 3, 2002, now patent 6,797,722, as the claims of the instant application are directed toward subject matter which was not disclosed in the parent application. Accordingly, for the purposes of examination and the application of prior art, the effective filing date of the present application is considered to be the filing date of PCT/IT03/00237, April 15, 2003.

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the term "effective amount," but fails to state the function which is to be achieved even though more than one effect can be implied from the specification. Is it a "effective amount" to reduce inflammation? Or, is it an "effective amount" to control the symptoms of uveitis? Or, is it an "effective amount" to induce immunosuppression in the host? This limitation is indefinite because it is not clear what "effective amount" means.

It is noted that this rejection may be overcome by replacing the confusing term with the language "effective amount to reduce the symptoms of uveitis" provided support is found in the specification as originally filed.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10 are rejected under 35 USC 102(b) as being anticipated by Mistrello et al.

As stated in the previous Office action, Mistrello et al. disclose a method of studying the immunological profile of DL111-IT, as known as 3-(2-ethylphenyl)-5-(3-methoxyphenyl)-1H-1,2,4 triazole. Specifically, Mistrello et al. teach administering effective amounts (2mg/kg/day) of DL111-IT to female rats with polyarthritis, which is an

autoimmune disease. The results demonstrate that DL-111-IT is an effective immunosuppressant. Please see the abstract; page 165, Adjuvant arthritis; page 168, first full paragraph. Uveitis is also an autoimmune disease.

The claims are anticipated by Mistrello et al. because Mistrello et al. teach administration of the identical active agent, i.e. 3-(2-ethylphenyl)-5-(3-methoxyphenyl)-1H-1,2,4 triazole, to a host in need thereof, using applicant's claimed method steps. Thus, the effect achieved in treating uveitis is an inherent property of the active agent.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mistrello et al., supra, in further view of Mozes et al. (Genetic Analysis of Experimentally Induced Lupus in Mice, Clinical Immunology and Immunopathology, 1997, 85(1):28-34).

Mozes et al. teach DBA, BXD RI, and C57BL/6 mouse strains models for inducing experimental Systemic lupus erythematosus (SLE) autoimmune disease in said mouse strains which has the serological and clinical manifestations characteristic of SLE in humans (page 28, column 1, line 6 to column 2, line 39), while Mistrello et al. teach C6D, B6D, C57B1, C3H and DBA female mouse strains and Wistar rats as experimental models for evaluating the immunosuppressive effects of DL111-IT with respect to inhibiting the antibody response to both thymus-dependent (SRBC) and thymus-independent (LPS) antigens and cellular response (DTH) to SRBC (page 164, second paragraph, and page 168, first full paragraph). Mistrello et al. and Mozes et al. do not teach uveitis, however.

Claim 11 is directed to human. Mistrello et al. teach mammal. Based on the desirable therapeutic benefits achieved in the female mice with polyarthritis and the expressed need for more selective and less toxic immunosppressants at the time the instant invention was created, Mistrello et al. suggest that DL111-IT would be useful as a therapeutic agent in clinical medicine (see Mistrello et al, pages 163 and168). Thus, someone of skill in the art would have found it obvious to combine the teaching of Mistrello et al., in view of Mozes et al., to create the inventive concept of the instant application with a reasonable expectation of success that DL111-IT would be effective as an immunosuppressant in humans suffering from uveitis.

A copy of the prior art reference Mistrello et al. (Immunological Profile of DL111-IT, a New Immunosuppressent Agent, Immunopharmacology, 10 (1985) 163-169) is not included as it is already made of record by applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 8 a.m. to 4:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 November 2006
CER

Ardin H. Marschel 11/25/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER